

REMARKS

Reconsideration of the present application is respectfully requested in view of the following remarks. Claims 33-86 are pending in the application; claims 73-80 are currently under examination, and claims 33-72 and 81-86 are withdrawn. Notwithstanding the grounds for any rejection, claims 73 and 76 are amended to more particularly point out and distinctly claim certain embodiments of the Applicant's invention. No new matter was added by the amendments. Support for the amendments can be found in the specification as filed, for example, on page 9, lines 24-25.

In addition, Applicant respectfully points out that the instant Office Action Summary incorrectly states that claims 79 and 80 are withdrawn, when, in fact, these claims are not only currently under examination, but have been acknowledged by the Examiner as containing allowable subject matter (*see* the Office Action of October 2, 2007). Acknowledgement of this typographical error is kindly requested.

REJECTIONS UNDER 35 U.S.C. § 103

The Examiner rejects claims 73-78 under 35 U.S.C. § 103(a) for alleged obviousness over WO 93/23069 ('069). The Examiner asserts that '069 teaches a composition comprising two or more isoflavone components, including formononetin and biochanin A, but agrees that '069 does not disclose a composition wherein the level of biochanin A is about 10% w/w or less of the isoflavone content. The Examiner, however, asserts that this level is inherent in "biochanin A compounds," which Applicant presumes to mean the biochanin A-containing compositions of '069, and further asserts that an intended use for a composition is of little patentable weight.

Applicant traverses this rejection and submits that the instant claims satisfy the requirements of non-obviousness. In particular, as previously made of record, Applicant submits that the Examiner has not established a *prima facie* case of obviousness with respect to the presently claimed subject matter. *See In re Mayne*, 104 F.3d 1339 (Fed. Cir. 1997) (The USPTO has the burden of showing a *prima facie* case of obviousness). The Examiner must at a minimum demonstrate that the combined references teach or suggest all the claim features, and

even assuming, *arguendo*, that the combination of references teaches each claim feature, the Examiner must provide an explicit, apparent reason to combine these features in the fashion claimed by the Applicant with a reasonable expectation of success. *See KSR v. Teleflex, Inc.*, No 04-1350 at 4, 14 (U.S. Apr. 30, 2007) (“A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art”). Here, ‘069 fails to teach or suggest a composition comprising an effective amount of formononetin and biochanin A, wherein the level of biochanin A is about 10% w/w or less of the isoflavone content, and wherein genistein, if present, is in the amount of about 5% w/w or less.

‘069 fails to expressly teach or suggest each feature of the instant claims. As acknowledged by the Examiner, ‘069 does not disclose an isoflavone composition wherein the level of biochanin A is about 10% w/w or less of the isoflavone content. Moreover, as previously made of record, ‘069 fails to disclose an isoflavone-based composition as above, in which the isoflavone content favors formononetin instead of genistein, such as wherein genistein, if present, is in the amount of about 5% w/w or less, as recited in the instant claims.

In addition, and contrary to the Examiner’s assertion, ‘069 fails to inherently teach or suggest each feature of the instant claims. In particular, Applicant respectfully disagrees with the Examiner’s assertion that the isoflavone content of the presently claimed composition represents an inherent feature of biochanin A compounds, let alone the compositions described in ‘069. Rather, in relying on an inherency theory, the burden of proof lies with the Examiner to provide extrinsic evidence that *makes clear* that the missing descriptive matter (*i.e.*, formononetin-based composition having about 10% w/w or less biochanin A and about 5% w/w or less genistein) is *necessarily present* in the compositions of ‘069. M.P.E.P. § 2112 (IV), citing *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Moreover, Applicant notes that inherency may not be established by *probabilities* or *possibilities*, and the mere fact that a certain characteristic *may* occur or be present in the prior art is *not sufficient* to establish the inherency of that characteristic. *Id.* Here, the Examiner not only acknowledges that ‘069 fails to disclose each feature of the instant claims, but provides no *required* extrinsic evidence to support the conclusory assertion that ‘069 inherently discloses an isoflavone composition, as presently claimed, which is modified to favor the presence of formononetin, and contains little, if any,

genistein. Indeed, as previously made of record, '069 teaches that formononetin is the least therapeutic of the isoflavones, and, therefore, fails to suggest modifying the ratio of an isoflavone composition in favor of formononetin, as recited in the instant claims. As such, '069 fails to teach or suggest, expressly or inherently, each feature of the instant claims, and, therefore, fails to provide the minimal requirements of a *prima facie* case of obviousness.

In addition, Applicant respectfully disagrees with the Examiner's assertion that an intended use of a claimed composition is of little patentable weight (*see* the Action, page 4). Rather, as here, a statement of intended therapeutic use for a novel composition may be relied upon to demonstrate that a person of ordinary skill in the art would have had no motivation to make that composition with a reasonable expectation of success. For example, the Federal Circuit in *Takeda* upheld the non-obviousness of claims directed to a novel compound, despite the assertion that the compound represented a straightforward derivative of a known compound, which, supposedly, would have otherwise been "obvious to try." *Takeda Chemical Industries v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007). In particular, the Federal Circuit relied on evidence that a person of ordinary skill in the art would not have been motivated to utilize the known compound with a reasonable expectation of success in generating the claimed compound for the intended therapeutic purposes described in the application. *Id.* at 1357, 1358, and 1361. Given the court's reliance on such evidence, the intended therapeutic use of a novel compound or composition is highly relevant to patentability, and, therefore, must be considered in determining whether a person of ordinary skill in the art would have been motivated to make the same with a reasonable expectation of success.

Here, the evidence of record provides no motivation to modify the isoflavone ratio of a therapeutic composition in favor of formononetin with a reasonable expectation of success, especially for the purpose of treating or reducing menopausal symptoms in a post-menopausal woman. Rather, as previously made of record, '069 emphasizes the importance of genistein's therapeutic biological activities, and de-emphasizes the importance of formononetin (*see, e.g.*, '069, page 9, paragraphs 5-6). '069 relies mainly on genistein and daidzein, and teaches that it is prudent that these isoflavones be present in approximately equal proportions (*see, e.g.*, '069, page 10, paragraph 3); suggesting that the presently claimed, formononetin-

based compounds would have little, if any therapeutic biological activity. In contrast, as also previously made of record, the instant application teaches that desirable clinical results may be achieved regardless of whether genistein and daidzein are both present in an isoflavone-related composition, let alone whether these particular isoflavones are present in approximately equal proportions (*see, e.g.*, Example 6 on page 18 of the specification). The instant application, therefore, describes unexpected therapeutic qualities associated with the use of formononetin (*see, e.g.*, Examples 6 & 7, on page 18, lines 1-25), which qualities are surprising in view of the prior art understanding that demethylation of formononetin improves biological efficacy, and that formononetin has the least activity of all the isoflavones. Accordingly, the evidence of record not only fails to provide a person of ordinary skill in the art with the motivation to formulate a formononetin-based composition with a reasonable expectation of success, as presently claimed, but supports the non-obviousness of the instant claims by empirically describing “new and unexpected results relative to the prior art.” *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004).

Since the evidence of record fails to teach or suggest, inherently or otherwise, each feature of the instant claims, and further fails to provide a motivation to arrive at the presently claimed subject matter with a reasonable expectation of success, Applicant submits that the Examiner has not established a *prima facie* case of obviousness over the instant claims. Applicant submits that claims 73-78 satisfy the requirements of obviousness under 35 U.S.C. § 103, and respectfully request reconsideration and withdrawal of this rejection to the claims.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The Examiner provisionally rejects claims 73-78 for alleged nonstatutory obviousness-type double patenting over claim 1 of co-pending U.S. Application No. 10/611,087 ('087). The Examiner agrees that it would not have been obvious to modulate the ratios of formononetin and biochanin A, as recited in claim 73, but asserts that claim 1 of the '087 application is drawn generally to a composition comprising formononetin and biochanin A. The Examiner then asserts that since the above-noted claims read on similar compositions, the double patenting rejection is proper.

Applicant traverses this rejection. Nonetheless, since this is a provisional rejection, Applicants will address the above-noted issue upon indication of allowable subject matter in either claims 73-78 of the instant application, or in claim 1 of the '087 application.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, INDEFINITENESS

The Examiner rejects claims 73-78 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. The Examiner is unclear as to the meaning of the recitation "less than about."

Applicant traverses this rejection and submits that the instant claims are clear. Nonetheless, Applicant notes that claims 73 and 76 have been amended to recite, for example, "wherein genistein, if present, is in the amount of about 5% w/w or less," thereby obviating this basis for the Examiner's rejection as it relates to the recitation "less than about."

Applicant submits that the instant claims satisfy the requirements of definiteness under 35 U.S.C. § 112, second paragraph, and kindly requests withdrawal of this rejection to the claims.

Applicant believes that all of the claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
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